POPH90119 Design of Randomised Controlled Trials

Credit Points:	12.50
Level:	9 (Graduate/Postgraduate)
Dates & Locations:	2011, Parkville This subject commences in the following study period/s: Semester 2, Parkville - Taught online/distance. Distance
Time Commitment:	Contact Hours: None Total Time Commitment: 8-12 hours total study time per week
Prerequisites:	-

Subject	Study Period Commencement:	Credit Points:
POPH90016 Epidemiology	Semester 1, Semester 2	12.50
POPH90015 Mathematics Background for Biostatistics	Semester 1, Semester 2	12.50

Corequisites:	None
Recommended Background Knowledge:	None
Non Allowed Subjects:	None
Core Participation Requirements:	None
Coordinator:	Prof John Carlin
Contact:	Professor Phil Ryan, University of Adelaide Biostatistics Collaboration of Australia Email: bca@ctc.usyd.edu.au Website: www.bca.edu.au OR Academic Programs Office Melbourne School of Population Health Tel: +61 3 8344 9339 Fax: +61 3 8344 0824 Email: sph-gradinfo@unimelb.edu.au
Subject Overview:	Topics include: principles and methods of randomisation in controlled trials; treatment allocation, blocking, stratification and allocation concealment; parallel, factorial and crossover designs including n-of-1 studies; practical issues in sample size determination; intention-to-treat principle; phase I dose finding studies; phase II safety and efficacy studies; interim analysis and early stopping ; multiple outcomes/endpoints, multiple tests and subgroup analyses, including adjustment of significance levels and P-values; reporting trial results and use of the CONSORT statement.
Objectives:	To enable students to understand and apply the principles of design and analysis of experiments, with a particular focus on randomised controlled trials (RCTs), to a level where they are able to contribute effectively as a statistician to the planning, conduct and reporting of a standard RCT.
Assessment:	Three written assignments submitted during the semester; Two worth 30% each (approx 10 hours work each) and one worth 40% (approx 12 hours work).

Prescribed Texts:	Piantadosi, S. Clinical Trials: A Methodological Perspective, 2nd ed, John Wiley & Sons, New York, 2005 (ISBN 978-0-471-72781-1) Resources Provided to Students: Printed course notes and assignment material by mail, email, and online interaction facilities.
Breadth Options:	This subject is not available as a breadth subject.
Fees Information:	Subject EFTSL, Level, Discipline & Census Date, http://enrolment.unimelb.edu.au/fees
Generic Skills:	Independent problem solving, critical appraisal of research literature, clarity of written expression, sound communication of technical concepts
Links to further information:	http://www.sph.unimelb.edu.au
Notes:	This subject is not available in the Master of Public Health.
Related Course(s):	Master of Biostatistics Postgraduate Certificate in Biostatistics Postgraduate Diploma in Biostatistics